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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In re Bard IVC Filters Products Liability Litigation	NO. MD-15-02641-PHX-DGC **THE PARTIES' PROPOSED AGENDA AND DISCUSSION OF ISSUES SUBMITTED PURSUANT TO THE COURT'S SEPTEMBER 15, 2015 ORDER SETTING INITIAL CASE MANAGEMENT CONFERENCE**

In the Order dated September 15, 2015, setting the initial case management conference, the Court directed the parties to "submit a proposed agenda, along with a discussion of all issues that should be addressed at the outset of this case." The Court specified a number of issues to be addressed, and invited the parties to identify any other matters for the Court to consider.

Consistent with that Order, counsel for the parties have extensively conferred by e-mail, by the exchange of draft submissions, and with an in-person meeting held in Phoenix, Arizona, on October 1, 2015. Counsel for all plaintiffs were invited to participate in these discussions, although a number of the plaintiffs' attorneys designated a single spokesperson to speak on their behalf. The principal attorneys participating in

those discussions were the following:

Ramon Rossi Lopez, Esq.
Troy Alexander Brenes, Esq.
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100 Bayview Circle
Suite 5600
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(Counsel of record for plaintiffs
Cason, Coker, Fox, Green, Murray, Smith, Tillman, and Wyatt)

Robert W. Boatman, Esq.
Shannon Clark, Esq.
Paul Stoller, Esq.
Mark S. O'Connor, Esq.
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C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.)

As an outgrowth of those discussions, the parties submit the following proposed agenda and discussion of issues for the Court's consideration:

1. PROPOSED AGENDA

A proposed agenda is attached as Exhibit "A."

2. ISSUES IDENTIFIED BY THE COURT

a. Are there categories of cases that raise different common issues, or do all of the cases raise all of the common issues?

(i) The Plaintiffs' Position:

This MDL involves all claims related to Defendants' Inferior Vena Cava filers;

which include the Simon Nitinol, Recovery®, G2®, G2® Express, G2® X, Eclipse®, Meridian® and Denali® Filters, as well as the delivery and retrieval systems used with these devices. Plaintiffs assert that while some categories of cases may raise different issues, there are common issues with all of the cases and that these common issues predominate over any distinctions between the cases.[1] Plaintiffs agree that much of the discovery already taken in individual cases at the federal and state level will apply to all cases, but note that substantial further discovery is still required.

All of these filters were cleared and marketed for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava under certain situations. Thus, all of these filters have the same indicated uses and are exposed to the same *in vivo* forces once deployed, which depending on the design and manufacture of the device may or may not cause a failure. With the exception of the Simon Nitinol filter, all of Bard filters have had, at one point or another, the additional marketing claim of being able to be retrieved after placement. Further, Defendants obtained clearance to market these devices through the 510k process, swearing under oath that each successive filter was substantially equivalent in respect to safety, efficacy, design, materials, and intended use as the predicate device, which started with Simon Nitinol Filter.

The Recovery® Filter was a modified design of the Simon Nitinol Filter, which was supposed to be as safe and efficacious as the Simon Nitinol Filter, but was supposed to allow the additional option of retrieval. Plaintiffs allege that each modification after the Recovery Filter was an attempt by Bard to correct a known design and/or manufacturing defect with its filters. In each case, Plaintiffs allege that Defendants failed to conduct sufficient testing to understand the anatomy of where the device would be used, what forces it would be exposed to after implant, or to ensure that the device would perform safely when used in a reasonably foreseeable manner. Plaintiffs further allege that Defendants continued to market devices they knew to have manufacturing and design

[1] The exception to this statement may be cases wherein a health care provider has been joined a defendant.

defects until a redesigned filter was cleared by the FDA, so as not to have to declare a recall and lose market share and profits. Even once the newer and safer devices, at least according to Defendants, were cleared, Defendants continued to sell the older less safe devices until inventory was exhausted. Plaintiffs also allege that Defendants consistently concealed and misrepresented safety, efficacy, and performance information regarding their filters, including that Defendants knew their filters exposed patient's to unreasonably high rates of failure and injury and that these risks were substantially higher than with other available devices. At this point in time, Defendants have stopped selling all filters but the Simon Nitinol and Denali Filters, but no recall has been issued for the prior products.

The failure modes in the cases currently consolidated before this Court involve claims of loss of structural integrity (fracture), loss of stability (migration, tilt and twisted legs), perforation, stenosis, thrombosis, and inability to retrieve. These failure modes are interrelated. For example, Bard's witnesses and/or internal documents have revealed that loss of stability (migration, tilt) leads to increased risk of perforation and fracture, and that perforation leads to an increased risk of fracture, stenosis, entire device migration, thrombosis, and inability to retrieve the device with long term exposure to future failures.

Plaintiffs allege the Recovery Cone, the device used to retrieve the Recovery and G2 Filters, is at issue in this litigation as according to Defendants it is the only safe way to remove these filters. However, the retrieval device was never cleared by the FDA, which means that thousands of people have been exposed to an unregulated device; which may have caused failed retrieval attempts, other device failures and injuries; and many thousands more now have no safe way to remove what they were told was a retrievable device. Further, the FDA and the medical literature now warn that the risk of device failure increases as the device remains in the body for a longer time.

Thus, common questions, *inter alia*, will consist of: (1) how did Defendants' understanding of the anatomy of the vena cava and testing used to simulate forces a filter would be exposed to therein changed over time; (2) what forces, conditions, design or

manufacturing issues are causing Defendants' filters to fail; (3) whether there are safer alternative designs and when did these become feasible; (4) whether Defendants established and maintained adequate procedure to monitor, report, and respond to post-market safety information; (5) whether Defendants established and maintained appropriate manufacturing procedures and how and why these changed over time; (6) whether Defendants were on notice of unacceptably high failure rates and/or that their devices exposed patients to increased risk versus other available treatment options; (7) whether Defendants timely and adequately acted to fix known design and manufacturing defects and/or should have removed the devices from the market; (8) whether Defendants provided adequate warnings; (9) whether Defendants offered warranties, promoted unproven benefits, or marketed the devices for off-label use; (10) whether Defendants concealed and misrepresented safety and efficacy information; (11) whether Defendants' devices are adulterated and misbranded under federal law; (12) whether Defendants engaged in conduct in conscious disregard of the rights and safety of others and/or fraud.

(ii) <u>The Defendants' Position</u>:

All of the cases in this MDL involve retrievable inferior vena cava ("IVC") filters designed and manufactured by C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard"). Those devices are utilized by physicians for the same medical purpose: to prevent blood clots from traveling to a patient's heart or lungs. Contrary to the plaintiffs' arguments, those devices save lives. Countless physicians throughout the country make medical determinations on a daily basis that the benefits of the devices outweigh the risks associated with all filters. Those risks, which include the complications alleged in this litigation, are known risks that are subject to guidelines promulgated by the medical community. The evidence demonstrates that Bard filters have complication rates significantly below those guidelines.

Over the years, Bard has sold six different generations of its retrievable filters. The cases pending in this MDL involve five different generations of the device. (None of the constituent cases in the MDL involve the current retrievable filter sold by Bard, the

Denali® Filter, or Bard's permanent filter, the Simon Nitinol® Filter). As of this date, the numbers of cases pending in this MDL involving each filter are as follows:

Simon Nitinol® Filter	0 cases
Recovery®	5 cases
G2®	32 cases
G2®X	7 cases
Eclipse®	7 cases
Meridian®	3 cases
Denali®	0 cases

Although each filter model shares some basic similarities in design, there are distinct differences in the devices that impact significant design attributes such as dimensions and finish. As a consequence, the design history of each filter has some variation, and the performance data for each model differs significantly.

Additionally, the complications alleged by the plaintiffs often differ. Some of the plaintiffs allege that their filters have migrated, while some claim that the devices have fractured. Other plaintiffs claim that their filters have tilted or perforated the wall of the inferior vena cava. A few plaintiffs allege a combination of those complications. The injuries allegedly related to those complications also vary widely. Some of the plaintiffs allege that their complications necessitated invasive surgery, while others are asymptomatic.

Substantial discovery has already been accomplished in the litigation that will apply to all of the cases. However, there remain substantial differences among the cases that will impact the preparation and trial of each case.

b. Some cases in this MDL have been pending for years and are ready for trial; others are newly filed. What should be done given the varying ages of cases in this MDL?

(i) <u>The Plaintiffs' Position</u>:

<u>Further Discovery</u>. Further discovery is required in even the more advanced cases for several reasons. First, Defendants have refused to update prior collections of electronically stored evidence, which in many cases has not been collected since 2005. Second, several new important discovery matters have come to light such as the FDA warning letter in July 2015 and an NBC news story in which a former regulatory specialist employed by Defendants revealed that her signature had been forged on a key submission to the FDA. Third, Defendants have consistently taken the position in these cases that discovery was limited due to "proportionality" in light of the amount in controversy of the individual case in which the discovery was taken. In particular, Defendants took the position in the individual suits that it was not required to conduct comprehensive searches of its ESI under the proportionality standard of Rule 26 due to the size of those individual cases. As a result, no plaintiff (even those in the most mature cases) has had the opportunity to take the full discovery from Bard. Now that these dozens (and soon to be hundreds) of cases have been consolidated in this MDL, plaintiffs believe that the proportionality analysis favors further collection and production of relevant materials.

Plaintiffs propose a discovery plan that will allow both new and previously-filed cases to proceed expeditiously through the MDL process, taking advantage of the discovery, depositions, and document production already done and that which will occur in the MDL. The further discovery necessary for these cases is identified in Section 2.d.(ii)1 *infra*.

<u>Remand</u>. Plaintiffs' counsel who represent clients who had existing trial dates prior to the formation of this MDL agree to adhere to Plaintiffs' proposed schedule in Section 2.i.(1) *infra*. The Rule 26 Reports and depositions of experts and others taken in these mature cases will be supplemented by any new discovery evidence and/or

testimony, as deemed appropriate.

Plaintiffs have identified three Plaintiff's cases that were the most advanced from a trial-readiness standpoint that can be remanded back to the Transferor Courts, commencing November 5, 2016:

Jennifer R. Coker(USDC, NORTHERN DISTRICT OF GEORGIA, ATLANTA DIVISION)

Lessie Tillman(USDC, MIDDLE DISTRICT OF FLORIDA, JACKSONVILLE DIVISION

Pamela Cason (USDC, NORTHERN DISTRICT OF GEORGIA,ATLANTA DIVISION

(ii) The Defendants' Position:

This MDL is in many ways unique because of the widely varying procedural postures of the cases. As the Court's order noted, a number of the cases are essentially ready (or nearing readiness) for trial, while others are newly filed. There are a total of 13 cases in which discovery is either complete or nearly complete:

Plaintiff	Original Jurisdiction
1. Cason, Pamela	GA – N.D. Ga. 1:12-cv-1288
2. Coker, Jennifer	GA – N.D. Ga. 1:13-cv-515
3. Conn, Charles	TX – S.D. Tex. 4:14-cv-298
4. Ebert, Melissa	PA – E.D. Pa. 5:12-cv-1253
5. Fox, Susan	TX – N.D. Tex. 3:14-cv-133
6. Henley, Angela	WI – E.D. Wis. 2:14-cv-59
7. Keen, Harry	PA – E.D. Pa. 5:13-cv-5361
8. Milton, Gary	GA – M.D. Ga. 5:14-cv-351

Plaintiff	Original Jurisdiction
9. Mintz, Jessica	NY – E.D.N.Y. 2:14-cv-4942
10. Ocasio, Denise	FL – M.D. Fla. 8:13-cv-1962
11. Rivera (McClarty), Vicki	MI – E.D. Mich. 4:14-cv-13627
12. Smith, Erin	TX – E.D. Tex. 1:13-cv-633
13. Tillman, Lessie	FL – M.D. Fla. 3:13-cv-222

Bard recognizes, however, that the plaintiffs believe additional discovery is necessary in all cases. Before the Judicial Panel of Multidistrict Litigation ("JPML"), the plaintiffs insisted that the issuance of an FDA warning letter to Bard on July 13, 2015, necessitated reopening discovery in all cases. Bard believes that the issues raised by the FDA's warning letter have little, if any, relevance to the issues presented by the cases pending in this MDL. For example, the plaintiffs argue throughout this submission that they need to launch discovery regarding the Recovery® Cone (a separate device used to retrieve Bard's filters). In ten years of litigation, however, Bard has never had a single case alleging an injury attributable to the Recovery® Cone. Nor do any of the present cases allege an injury related to the device. Still, Bard acknowledges that the broad scope of permissible discovery under the Federal Rules of Civil Procedure justifies some targeted discovery pertaining to the warning letter, even in cases where discovery has otherwise closed. Given these considerations, Bard recognizes that a brief period of discovery may be necessary before any cases are ready for trial.

Following the completion of that targeted discovery, Bard believes that the interests of efficiency – for this Court (as well as all impacted federal courts) and the parties – favor establishing a bellwether process that would involve the selection of a group of potential bellwether cases (perhaps 5 to 7 cases) from the pool of 13 cases in which most discovery is completed. Bard also respectfully suggests that the parties

consider waiving their right to require remand of the bellwether candidates, as required by the U.S. Supreme Court's decision in *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998), and if the Court is willing, have this Court try at least the initial bellwether cases in this MDL.

If the Court were to adopt this process (or a variation thereof), the parties and the Court could develop a schedule and procedure for identifying the bellwether pool, completing discovery in those cases, and handling any remaining dispositive motions. Bard believes that this process could lead to the first bellwether case being ready for trial in approximately 12 months.

c. *Should a document depository of some sort be created?*

Five law firms[2] have led this litigation on behalf of Plaintiffs with regard to the vast majority of the document discovery that has been taken. These five law firms and their associated counsel have set up and funded an online virtual document depository. Plaintiffs' counsel from these firms will work cooperatively with all Plaintiffs' counsel with cases transferred into this MDL to facilitate access to previous productions and discovery and disclosures in the MDL.

Because the depository for plaintiffs is currently established and coordination for access merely awaits a definitive Order from this Court establishing a Plaintiff's Steering Committee, Plaintiffs are ready and able to accept further productions responsive to currently pending discovery immediately and on a continuing basis.

d. Have the parties established an ESI protocol that is being used in some or all of the cases?

(i) <u>Format of Production</u>

The parties are in the process of negotiating a proposed Case Management Order regarding the format of production. If the parties cannot reach agreement on this matter within 30 days, they will request a briefing schedule from the Court.

[2] Lopez McHugh, Heaviside Reed Zaic, Babbitt Johnson, Law Office of Ben C. Martin, and Karon & Dalimonte.

(ii) Scope of Discovery and ESI Issues

1. The Plaintiffs' Position:

In litigating the individual cases that have been transferred to this MDL (as well as those pending in State courts), Defendants have consistently acted to prevent discovery that would be necessary to satisfy the discovery needs of all Bard IVC Filter cases. Specifically, when plaintiffs have tried to negotiate discovery protocols that would satisfy the discovery needs of all plaintiffs, Defendants repeatedly objected that under the "proportionality" analysis of Rule 26(b)(2)(C) the court could only consider the amount in controversy in the individual case and whether or not the requested materials were relevant to the facts of the individual case. Moreover, despite the ongoing manufacturing and sale of Bard IVC filters as well as ongoing claims and complaints, Defendants have refused to collect and produce updated ESI, which in many cases has not been collected since 2005. Defendants have also refused to collect and produce ESI from custodians and sources regarding Bard's later generation devices, including the Eclipse, Meridian and Denali filters; or the Simon Nitinol Filter.

In light of the large number of cases and injuries (and, therefore, damages), new time frames and devices, and new discovery matters that have come to light— e.g. the FDA warning letter—in this MDL, plaintiffs believe that Defendants' prior imposed discovery limitations based on "proportionality" are inappropriate and that plaintiffs should be permitted broad and full discovery of all relevant information. Generally speaking, plaintiffs request that prior ESI and document collections be updated and that additional custodians or ESI sources with relevant information be collected and produced. To that end, plaintiffs believe that discovery and disclosure of Bard's ESI systems, systems architecture, custodians, and how and where information is stored are necessary to determine appropriate ESI and discovery protocols with respect to how those systems should be searched for relevant information.

In the meantime, plaintiffs provide the below list of discovery materials that should be expedited immediately in this proceeding. The majority of this list is comprised of

discovery requests that are outstanding and/or pending in one or more of the cases that have now been transferred as related cases to this MDL.

DOCUMENT AND ESI PRODUCTION

1. Updated (2010 to present) complaint (adverse event) files relating to the Recovery, G2, G2X, G2 Express filters. Plaintiffs also seek production for complaint files related to the Simon Nitinol, Eclipse, Meridian and Denali filters which have not been produced in previous productions. Plaintiffs also seek production of previously withheld failure modes, e.g., occluded/thrombosis, stenosis, twisted legs, failed retrieval attempts and tilted filters.

2. Updated versions of Bard's Adverse Event Tracking Systems known as Easy Track and Trackwise.

3. Updated collections and production of previously searched "custodians" and ESI sources.

4. Collection and production of ESI from custodians involved with later generation filter devices or employed at later times frames.

5. Updated privilege logs.

6. All documents and ESI relating to the FDA inspections and July 2015 "warning letter" finding, among other things, Bard's IVC filters and Recovery Cone Removal Devices to be adulterated and misbranded under federal law. This includes all communications with the FDA, all internal communications, and all notes regarding the inspections and the FDA findings.

7. The complete custodial files (updated if previously produced) of anyone that has knowledge relating to the FDA warning letter, whether directly involved with interactions with FDA officials or not. For example, this would include, among others, all Bard employees and third parties who were copied on the warning letter.

8. ESI and documents that have previously been withheld as to Bard's later generation devices such as Eclipse, Meridian and Denali filters.

9. All documents and related material regarding Recovery Cone Removal System design, design changes, corrective actions, reasons why design changes were made, regulatory communications, and adverse event reports.

10. Custodial files of the sales hierarchy of all Territory Managers, Sales Trainers, District Managers, and Regional Managers involved in the sales and marketing of the entire line of Bard IVC filters beginning with the Simon Nitinol Filter through and including the Denali.

2. <u>The Defendants' Position</u>:

Bard believes that the most significant issue presented in this MDL is the scope of additional discovery to be conducted. By contrast to other MDL proceedings, the parties do not enter into this MDL with a "clean slate" as to discovery. To the contrary, more discovery has already been accomplished in the Bard IVC filter litigation than would normally be conducted in a comparable MDL of this size.

By way of background, during an earlier phase of this litigation several years ago, Bard produced in excess of 2 million pages of documents (at a cost of more than $2 million). Those documents included ESI identified by the use of approximately 27 search terms applied across more than 70 individual custodians.

Thereafter, the attorneys for various plaintiffs presently involved in this litigation demanded the production of voluminous additional ESI from Bard. After full briefing on issues such as the format of production, the number of document/ESI custodians, and additional search terms, a federal magistrate in the case of *Kevin Phillips v. C. R. Bard, Inc., et al.*, Case No. 3:12-cv-00344-RCJ-WGC (D. Nev. March 1, 2013) (Dkt. No. 77) ordered the search and production of ESI from 20 additional custodians. The Magistrate in that case further permitted the plaintiffs to add 10 additional search terms to the 27 terms that Bard had already used. The search terms selected by those attorneys (who are now seeking a leadership role in this MDL) included "Meridian" and "Denali," which are the two most recent generations of Bard's IVC filters. (As a result of those further efforts, in 2013 alone, Bard produced over 500,000 pages of additional documents and spent over

$600,000 on ESI costs, which was in addition to the millions of dollars already spent).

In addition, over the course of this litigation, the plaintiffs have taken more than 80 depositions of Bard employees and consultants. Many (and probably a majority) of those depositions were taken by the same law firms seeking leadership positions in this MDL.

Despite the extensive amount of discovery already accomplished, the plaintiffs are attempting to initiate an expensive new wave of discovery. The extraordinarily broad discovery they now seek in many ways duplicates discovery that has been already accomplished in this mature litigation. By way of example, the plaintiffs are insisting on the following new discovery:

- "Updated collections and production of custodial files or previously searched custodians" (essentially seeking a "re-do" of all ESI discovery previously accomplished);
- "All documents and ESI 'relating to' the FDA inspections and July 2015 'warning letter'" (seeking without limitation all documentation even tangentially mentioning those events);
- "All documents reviewed by FDA as part of the inspections and investigation referenced in the July 2015 warning letter" (seeking a vast amount of material regardless of any relevance to the issues raised in the warning letter);
- "Custodial files of the sales hierarchy of all Territory Managers, Sales Trainees, District Managers, and Regional Managers involved in the sales and marketing of the entire line of Bard IVC filters beginning with the Simon Nitinol Filter through and including the Denali" (a request that would require searching the ESI of literally hundreds of past and present employees over a time span exceeding 15 years);
- Up to date custodial files for "anyone that has knowledge [of the FDA inspections and warning letters]" (a request broad enough to include virtually every employee of the company);

- All "complaint (adverse event) files" and all "ESI and documents" regarding the Denali® Filter (even though there is not a single Denali® case presently pending in this MDL, and Bard has never received any lawsuit before regarding that filer);
- All complaint files concerning the Simon Nitinol® Filter, a device that has been sold since the early 1990's (even though there is not a single case pending in this MDL regarding that filter); and
- Up to 25 additional corporate depositions (beyond the 80-plus depositions already accomplished).

Additionally, the plaintiffs have asked for a new series of corporate representative depositions that in large part duplicate numerous depositions that have already been taken. They have requested depositions of corporate witnesses on such broad topics as "post market surveillance and reporting," "sales and marketing," and "regulatory affairs," even though they have already deposed most of the Bard employees responsible for those areas over the years.

Bard recognizes that some additional discovery will be necessary, particularly regarding the FDA inspections and warning letters. However, Bard also believes that the federal rules mandate that the discovery be "proportional to the needs of the case." *See* Proposed Amendment to Fed. R. Civ. P. 26(b)(1). Bard submits that, in this context, a determination of how much discovery is proportionate for this MDL must take into account the millions of pages of documents already produced and scores of depositions already taken in this litigation.

Against that background, and in view of the discovery already accomplished, Bard would respectfully ask for the Court's guidance as to the scope of additional discovery appropriate for this MDL. Bard would then propose the following process for the parties to implement based on that guidance:

November 10, 2015: Deadline for Bard to produce all communications (including responses, progress reports, attachments, etc.) with the FDA regarding the "483" Inspection Reports and FDA warning letter.

December 2, 2015: Bard will present a corporate representative for a deposition on issues regarding the FDA inspections and warning letters (pursuant to Fed. R. Civ. P. 30(b)(6)).

December 16, 2015: Deadline for parties to meet and confer regarding (1) any additional discovery (document requests, ESI searches, and/or depositions) sought by the plaintiffs pertaining to the FDA inspections and warning letter; (2) any additional ESI custodians to be searched and key words to be utilized, consistent with any guidance provided by the Court as to the scope of additional discovery; and (3) any additional depositions of corporate witnesses and/or third-party consultants (again, consistent with any guidance provided by the Court).

January 6, 2015: Absent an agreement on the scope of additional discovery, the parties must submit proposals to the Court.

e. Have the parties agreed upon protective orders and Rule 502 orders that are being used in some or all of the cases?

Yes. In all but the most recently filed cases, the parties have agreed upon protective orders (with Rule 502(d) provisions) that have been entered by the various courts. The parties are prepared to propose a similar order for the Court's consideration in this MDL.

f. Will some of the cases raise jurisdictional or remand issues that need to be addressed early? If so, what are those issues and what cases are affected?

The parties are aware of one case (*Saviour*) wherein a non-diverse health care provider has been joined as a defendant. Defendants have removed the case based on a claim of fraudulent misjoinder. As an alternative basis for removal, Defendants claim that the healthcare provider should be severed and remanded from the case. A Conditional Transfer Order was entered for that case on October 2, 2015. Plaintiff's counsel for that

case takes the position that joinder of the health care defendant is proper and that the case should be remanded without unnecessary delay. Thus, Plaintiffs seek an expedited briefing schedule to have this matter decided.

g. Are there similar state court cases pending? If so, where and in what number? Has there been any coordination with state court cases thus far?

(i) Plaintiffs' Position:

Plaintiffs agree with the number and identity of the current state court cases listed by Defendants in their position statement below. It should be noted, however, that Plaintiffs understand that dozens or hundreds of new cases are expected to be filed in the next few months. Many of those cases may be filed in state courts. While the state courts are not subject to the MDL, Plaintiffs believe that the following issues will facilitate state/federal coordination.

Document Depository. To date, all discovery—whether related to state or federal cases—has been collected and stored in a common document depository. Continued coordination of state and federal cases is anticipated with regard to cases that have legal representation common to both state and federal cases.

Pending State Court Discovery. Plaintiffs recently met and conferred with Bard's counsel regarding coordinating state and federal discovery during the MDL stay of discovery. While the parties have committed to trying to coordinate all discovery when feasible, there remain two items Plaintiffs believe require the Court's immediate coordination.

(A) *Corporate Witness Deposition re: FDA Warning Letter* – There is one pending deposition notice[3] in both state and federal proceedings concerning the July 13, 2015 Warning Letter issued by the FDA regarding, *inter alia*, multiple violations of federal code sections (e.g., 12 C.F.R. 820.198(a)) regarding post-marketing surveillance related to Bard's IVC Filter products

[3] A deposition notice was served in a pending case pursuant to Florida Rules of Civil Procedure 1.310(b)(6), *Austin v. C.R. Bard, et al.*, CACE: 15-008373, Seventeenth Judicial Circuit, Broward County, Florida.

at issue in this litigation. Plaintiffs in a pending state court action (*Austin v. C.R. Bard et al*.) have been awaiting a document production and date for Defendants' selected corporate witness responsive to the above described notice since September 9, 2015. Plaintiffs' attorneys in the *Austin* matter have also entered an appearance in matters before this Court. While counsel for the *Austin* plaintiffs have sought this deposition since September, the meet and confer with Defendants has led to Bard's agreement to produce a witness to testify on behalf of Bard on December 2, 2015 with documents responsive to the accompanying *duces tecum* to be produced on November 10, 2015. Plaintiffs in the *Austin* matter and this MDL have agreed that the deposition will be cross-noticed for the MDL. This agreement is dependent upon this Court's discovery stay being lifted for the MDL. Plaintiffs therefore request that the stay currently in place be lifted at the October 29, 2015, hearing.

(B) *Subpoena Duces Tecum re: Public Relations Firm.* Plaintiff's counsel in the *Austin* case intend to serve a subpoena for records upon the public relations firm Hill & Knowlton. Hill & Knowlton assisted Bard with public relations matters related to its IVC Filter Products, and communications between the two companies were admitted into evidence at the *Phillips v. C.R. Bard et al.* trial in the District of Nevada in February 2015. A Notice of Production from Non-Party has been served on Bard and as of the date of this filing, Bard is still within its right to object to the issuance of such a subpoena from the Circuit Court of the Seventeenth Judicial Circuit in Broward County, Florida. Considering the process has begun in a state court action, Plaintiffs anticipate coordination of such production with the MDL on track with the state court efforts as the production and subsequent depositions are relevant to both state and federal actions and anticipate coordination efforts between the parties on this matter.

Creation of a State/Federal Liaison Position. Taking into consideration that some state court cases have been pending prior to the formation of this MDL and may currently or potentially have different discovery and trial schedules, Plaintiffs respectfully submit that coordination of state and federal efforts would be assisted by the creation of a state/federal court liaison position to report to the Court regarding opportunities to coordinate efforts between the state court cases in particular where those Courts' efforts might benefit the progress of this proceeding and vice-versa.

Stay of Dispositive Motions in Related State Court Cases. In order to efficiently and economically coordinate discovery between the pending federal and State Court actions, the parties in any related State Court cases agree to request stays of any dispositive motions until the proposed discovery period is completed.

(ii) The Defendants' Position:

There are presently 13 related cases pending in various state courts. Those cases are as follows:

STATE COURT CASES			
Plaintiff	**Jurisdiction**	**Assigned Judge**	**Plaintiff's Counsel**
1. Albaum, Victor	Superior Court in the State of California, County of San Mateo (Case No. CIV 5261606)	Hon. Robert D. Foiles	Thomas E. Rocket, III
2. Austin, Clare	Circuit Court of the Seventeenth Judicial Circuit in and for Broward County, Florida (Case No. 15-008373 Div: 07)	Hon. Jack Tuter	Joseph Johnson Julia Reed Zaic
3. Benzing, Kathleen	Superior Court of Arizona, County of Maricopa (Case No. CV2013-054323)	Hon. Susan Brnovich	Joseph Johnson Julia Reed Zaic Joshua Parilman
4. Della Salle, Eileen	Superior Court of New Jersey Law Division – Union County (Case No. UNN-L-4613-14)	Hon. Camille M. Kenny	Theodore Oshman Jason Pullman

5. Fraser-Johnson, Bianca and Michael	Superior Court of Delaware in and for New Castle County (Case No. N15C-09-207-CLS))	Hon. Calvin L Scott, Jr.	Richard A. Zappa Timothy E. Lengkeek
6. Furtado, Maria	Superior Court of New Jersey Law Division – Union County (Case No. UNN-L-4615-14)	Hon. Camille M. Kenny	Theodore Oshman Jason Pullman
7. Leus, George	Superior Court of New Jersey Law Division – Cumberland County (Case No. CUM-L-00830)	Hon. Richard J. Geiger	Joseph Johnson Michael S. Katz James J. McHugh
8. Moore, Elizabeth	Superior Court of Arizona, County of Maricopa (Case No. CV2014-008738)	Hon. Douglas Gerlach	John Dalimonte Teresa Toriseva Brett L. Slavicek James E. Fucetola
9. Schwall, Jenna	Supreme Court of State of New York, County of New York (Case No. 152891/12)	Hon. Kelly O'Neill Levy	Richard M. Steigman
10. Severns, Kristy	Superior Court of New Jersey Law Division – Union County (Case No. UNN-L-4616-14)	Hon. Mark P. Ciarrocca	Theodore Oshman Jason Pullman
11. Smith, Ted	Circuit Court of Shelby County, Alabama (Case No. 058-CV-2015-900817.00)	Hon. Hewitt Conwill	David H. Marsh Rip Andrews J. Ben Ford
12. Stesney, Joann	Superior Court of Arizona, County of Maricopa (Case No. CV2012-006103)	Hon. Joshua D. Rogers	John Dalimonte Teresa Toriseva Joshua Parilman
13. Tabb, Alice	Circuit Court of Montgomery County, Alabama (Case No. 03-CV-2015-900812.00)	Hon. Truman M. Hobbs	David H. Marsh Rip Andrews Walter McGowan Sanely F. Gay

Bard has attempted to coordinate discovery in those cases by sharing discovery previously accomplished in other cases to avoid duplication of efforts. However, Bard also believes the plaintiffs should likewise coordinate discovery, and is concerned that some counsel with cases in both this MDL and in state courts are simultaneously pursuing duplicative discovery in multiple forums.

h. Should a master complaint be filed for organizational purposes (not to supersede pending complaints in other cases)?

The parties agree that the creation of a master complaint, as well as a master answer, would be appropriate.

i. What discovery plan should be adopted in this case?

(i) <u>The Plaintiffs' Position</u>:

Plaintiffs propose a discovery plan that will allow both new and previously-filed cases to proceed expeditiously through the MDL process, taking advantage of the discovery, depositions, and document production already done and that which will occur in the MDL. Virtually all of what is set forth below has been previously discussed with Bard's counsel, in some instances dating as far back as early 2014, and continuing in greater depth and breadth over the past several months.

Plaintiffs have been and will continue to meet and confer with defense counsel regarding a list of corporate and third party witnesses not yet deposed by counsel currently representing plaintiffs in the MDL, as well as discussing which prior deponents need to be redeposed or whose testimony needs to be completed and/or supplemented. While parties who were not given the opportunity to participate in those prior depositions cannot be bound by them, there is a consensus among both state and federal court plaintiffs' counsel to adopt a significant amount of prior discovery, which would include a significant number of corporate, third party and expert witness depositions. The establishment of the plaintiffs' leadership group in the MDL will facilitate this coordination.

Plaintiffs' focus in this submission is on the discovery Plaintiffs are certain they need to expedite scheduling and completing during the early phases of this MDL. For the most part, the list is comprised of discovery requests that have been outstanding or pending in one or more of the cases that have now been stayed and transferred to MDL No. 2641.

<u>Documents and Electronically Stored Information</u>. The ESI collections and updates are discussed in Section 2.d.(ii)1, *supra*. Attached as Exhibit 1 is "Plaintiff's Frist

Requests For Production of Documents" served in the *Joseph Rowe* matter, which is now part of this MDL. While this does not represent all documents requests that will be served as part of the MDL proceedings, plaintiffs incorporate this Request for Production by reference. Plaintiffs ask that this discovery document be adopted as served upon defendants in this MDL proceeding.

Depositions. Prior to the assignment of this MDL, plaintiff's counsel served Rule 30(b)(6) deposition notices on or about July 29, 2015. Plaintiff's counsel specifically requested a Rule 30(b)(6) deposition on the subject of the July 2015 warning letter. Bard's counsel responded to this request on October 5, 2015, offering December 2, 2015, for the deposition.

In addition to the warning letter Rule 30(b)(6) deposition, plaintiffs have pending Rule 30(b)(6) deposition notices on the following issues:

1. Post market surveillance and reporting, the medical device equivalent of pharmacovigilance, adverse events, complaint files, MDRs, trending reports and analyses, databases and third party involvement in these matters.
2. FDA communications.
3. Sales and marketing.
4. Regulatory affairs (structure, policies, procedures, compliance), labeling, IFUs, Safety alerts and communications to stakeholders (doctors and patients).

The actual deposition notices dictate the nature, extent and details of the subject matters as well as the related documents plaintiffs seek. Plaintiffs agreed to put these depositions on hold in the federal proceedings pending further direction in the MDL, but requested that the documents requested in the notices be collected and readied for production well in advance of the dates scheduled for the depositions. Plaintiffs will have multiple deposition teams available to take these and other depositions within the MDL process even if some need to be taken on overlapping dates and during the same week. This commitment applies to all common benefit depositions in this MDL.

Proposed Dates. Plaintiffs propose the following scheduling order. This schedule

does not include a scheduling order for an MDL-sanctioned Bellwether Trial procedure. Instead, plaintiffs request that they be allowed to address that issue after the generic/common benefit scheduling order is entered by the Court, and after a reasonable period to meet and confer with defense counsel regarding same.

1. Nov. 1, 2015: The above-referenced Request for Production, Ex. 1, be deemed served, with responses due, including objections and privilege logs if applicable, by no later than Dec. 1, 2015 and production of documents to commence December 2, 2015 and be completed by Dec. 31, 2015.
2. November 25, 2015:
    a. All documents and ESI relating to the FDA inspections and July 2015 "warning letter" finding, among other things, Bard's IVC filters and Recovery Cone Removal Devices to be adulterated and misbranded under federal law. This includes all communications with the FDA, all internal communications and notes regarding the inspections and the FDA findings.
    b. The complete custodial files (updated if previously produced) of anyone that has knowledge of these matters, whether directly involved with interactions with FDA officials, or not. For example, this would include, among others, all Bard employees and third parties who were copied on the warning letter
    c. All documents and related material regarding Recovery Cone Removal System design, design changes, corrective actions, reasons why design changes were made, regulatory communication and adverse event reports;
    d. After meeting and conferring regarding pending privilege log issues and challenges, plaintiffs to file their first brief challenging specific documents and/or category of documents they want produced
3. December 2, 2015: 30(b)(6) deposition regarding July 2015 FDA Warning Letter;
4. December 3through December 17: Completion of remaining 4 previously noticed 30(b)(6) depositions;
5. November 15, 2015 through January 3, 2016:

a. Updated (2010 to present) complaint (adverse event) files relating to the Recovery, G2, G2X, G2 Express, Eclipse, Meridian and Denali filters;
b. ESI and documents that have previously been withheld as to Bard's later generation devices such as Eclipse, Meridian and Denali filters;
c. Updated versions of Easy Track and Trackwise;
d. Updated collections and production of custodial files or previously searched "custodian."
e. Updated privilege logs
f. ESI and documents that have previously been withheld as to Bard's later generation devices such as Eclipse, Meridian and Denali filters;
g. Custodial files of the sales hierarchy of all Territory Managers, Sales Trainers, District Managers, and Regional Managers involved in the sales and marketing of the entire line of Bard IVC filters beginning with the Simon Nitinol Filter through and including the Denali;

6. November 21, 2015: Six (6) boxed Recovery, G2, G2X, G2 Express, Eclipse, Meridian and Denali filters, as well as each and every version of Bard Removal Devices.
7. January 15, 2016: Plaintiffs will identify first 5-10 corporate and third party witnesses to be deposed, commencing February 1, 2016, and completed by April 15, 2016.
8. February 15, 2016: Plaintiffs will identify and additional 5-10 corporate and third party witnesses to be deposed, commencing March 15, 2016, and completed by May 1, 2016.
9. May 1 through May 31, 2016: Plaintiffs to complete depositions of common benefit corporate and third party witnesses, the total not to exceed 25, excluding 30(b)(6) witnesses.
10. July 15, 2016: Plaintiffs serve Rule 26 Expert Reports
11. July 30, 2016: Defendants to serve Rule 26 Expert Reports

12. August 18, 2016: Plaintiffs to serve Rule 26 Rebuttal Expert Reports
13. October 5, 2016: completion of Expert Witness depositions
14. Daubert challenges: filed October 20, 2016
15. Daubert hearings: early November 2016
16. Motions for Summary Judgment: November 2016

Remand. Plaintiffs' counsel who represent clients who had existing trial dates prior to the formation of this MDL agree to adhere to the above schedule. The Rule 26 Reports and depositions of experts and others taken in those cases will be supplemented by any newly discovery evidence and/or testimony, as deemed appropriate.

Plaintiffs have identified three Plaintiff's cases that were the most advanced from a trial-readiness standpoint that can be remanded back to the Transferor Courts, commencing November 5, 2016:

Jennifer R. Coker(USDC, NORTHERN DISTRICT OF GEORGIA, ATLANTA DIVISION)

Lessie Tillman(USDC, MIDDLE DISTRICT OF FLORIDA, JACKSONVILLE DIVISION

Pamela Cason (USDC, NORTHERN DISTRICT OF GEORGIA,ATLANTA DIVISION

Plaintiffs' counsel with advanced state court cases, assuming authorization by the state court Judge, will agree to not commence any state court trial until June 2016, so as to benefit from a cooperative and coordinated discovery effort with MDL process and assuming the above-referenced scheduling order.

Bellwether Trials (further details to follow):

February, 2017 – April 2017: 3-5 cases.

(ii) The Defendants' Position:

Taking into consideration the various issues set forth in this submission, Bard would propose the following discovery schedule:

(a.) November 16, 2015: Bard must file motion for protective order related to Lehmann report (see discussion in section "k", infra).

(b.) December 1, 2015: Discovery commences regarding FDA warning letter.

(c.) December 3, 2015: Plaintiffs must file any brief in opposition to Bard's motion for protective order.

(d.) December 14, 2015: Bard must file any reply brief in support of its motion for protective order.

(e.) January 4, 2016: Both sides provide Court with a recommendation of 6 (of the 13) cases to be included in the bellwether pool.

(f.) January 18, 2016: Court advises parties of 5-6 cases selected for initial bellwether pool.

(g.) January 29, 2015: Parties advise Court what (if any) additional discovery (beyond discovery related to the FDA warning letter) remains to be completed in the designated bellwether pool of cases.

(h.) February 1, 2016: Additional discovery begins in bellwether cases.

(i.) May 3, 2016: Any supplemental reports from previously-designated experts in the bellwether cases must be disclosed. In the event that a party believes it is necessary to designate a new expert, that party should seek leave of court (absent any prior agreement among the parties) prior to this deadline.

(j.) July 29, 2016: All discovery in the designated bellwether pool of cases should be completed.

(k.) August 31, 2016: All new or renewed dispositive and/or *Daubert* motions should be filed.

(l.) TBD Deadline: Deadline for filing motions in limine.

(m.) TBD Deadline: Date for trial of first bellwether case.

j. Should the case include alternatives to traditional written discovery such as fact sheets to be completed under oath by parties?

The parties agree that if the discovery plan calls for all cases in the MDL to

proceed with case-specific discovery, then fact sheets can be a streamlined method for the exchange of basic information. However, if the Court focuses instead on a limited subset of cases as part of a bellwether process, which the parties propose, a more cost-effective approach is to have each plaintiff and the Defendants complete a simple profile form at the outset of a case. The plaintiff profile form would provide basic census information (name, address, etc.), the identification of the product involved, a description of the alleged injury, and a brief summary of the medical treatment allegedly necessitated by the complication. The defendant profile form would provide basic information such as the relevant Territory Manager involved with the account, whether any complaints were filed regarding the Plaintiff, what the results were of any such investigations, and what marketing materials, labeling, or warning materials were sent directly to the prescribing physicians. Such basic forms, which take little time to complete, provide the Court and the parties with sufficient data to utilize when selecting representative cases for further work-up. Thereafter, in all cases chosen for further discovery, the parties would then complete more extensive fact sheets based on forms agreed upon by the parties.

k. Are there particular issues which, if resolved early, will significantly advance the litigation?

(i) The Lehmann Report

(a) The Plaintiffs' Position:

Plaintiffs agree that early attention to this issue would be beneficial; however, Plaintiffs disagree with Bard's position that a blanket *de novo* review of the document is appropriate. Considering there are disparate rulings regarding whether this document is privileged in different District Courts, the matter necessitates the Court's input as to how to manage these differing previous decisions. Indisputably, the Lehmann Report is a public record as it was admitted into evidence during trial in *Phillips v. C.R. Bard et al*[4] after its pre-trial privileged status was overturned as a result of an evidentiary ruling.

To summarize, in a pre-trial decision rendered by the Magistrate Judge in the

[4] *Phillips v. C.R. Bard et al.*, Nevada District Court, C.A.N. 3:12-cv-00344-RCJ-WGC.

Phillips matter, the Lehmann Report was deemed attorney work product and therefore privileged in the *Phillips* case. After that 2013 decision, which Defendants have heavily cited, several other state and federal courts relied on that ruling in also determining that the Lehmann Report was privileged. But that *Phillips* pre-trial decision was later overturned (as to the privileged status of the Lehmann Report only) by the trial judge and the Lehman Report was used in that trial. Plaintiffs have yet to re-challenge those other courts' decisions that had adopted, predicated, or cited the *Phillips* trial ruling as a basis for deeming the Lehmann Report privileged. The MDL petition was then filed and it was determined that the matter would be addressed once this litigation was centralized.

The decision during trial in the *Phillips* case is highly significant since it is the only case where the Lehmann Report was at issue and reached trial. The pre-trial phase did not allow the Magistrate the benefit of observing the totality of evidence in context as it all came in during trial, including testimony regarding the Lehmann Report. Moreover, and peculiar to these proceedings which requires early resolution, Bard has not been successful in convincing some state and federal courts that the Lehmann Report is attorney work product. This is a crucial point for consideration by this Court as those rulings were used in furtherance of discovery efforts already conducted in some cases now at bar.

For example, *Tillman v. C.R. Bard et al.* is a case that has been transferred to this MDL from the Middle District of Florida. Bard's assertion that the Lehmann Report is privileged was denied by the Magistrate Judge in 2014 and the decision upheld by the District Court Judge (Hon. Marcia Morales Howard) in a written opinion[5]. Therefore, the Lehmann Report has been used extensively in discovery and motion practice in that matter based on its availability and discovery has since closed. Plaintiffs respectfully suggest that such a decision prior to the creation of this MDL does not lend itself to a *de novo* review of the same document since it could potentially eviscerate the discovery

[5] Tillman v. C.R. Bard et al., Middle District Florida, 3:13-cv-00222-MMH-JBT, Doc. 170 (March 11, 2015).

accomplishments made to date in that case which Bard itself suggests should be considered as part of a bellwether process. (See, Defendants' position at section b. of this filing).

(b) The Defendants' Position:

Before the creation of this MDL, a recurring work-product claim has been litigated in multiple Bard filter cases. In preparing for anticipated and imminent litigation, Bard's Law Department contracted with Dr. John Lehmann for the preparation of a written report for submission directly to Bard's Law Department. Bard has consistently asserted that the work-product doctrine protects Dr. Lehmann's report from discovery and use in litigation.

Since early 2013, after Dr. Lehmann's report was inadvertently produced by an ESI vendor during discovery and then expeditiously clawed back, Bard has been forced to defend its work-product claim regarding Dr. Lehmann's report in state and federal courts across the country. In June 2014, the United States District Court for the Northern District of Texas in *Alexander v. C. R. Bard, Inc.* held an extensive evidentiary hearing at which Dr. Lehmann and Bard's Assistant General Counsel who hired him testified and were cross examined for approximately three hours about the creation of Dr. Lehmann's report. (The plaintiff was represented by John Dalimonte and Ben Martin, two of the lead counsel for the plaintiffs in the MDL.) During the evidentiary hearing, Bard also submitted approximately sixty documents in support of its work-product claim. After considering the testimony and exhibits, the *Alexander* Court, applying the most restrictive work-product test in the country (the "primary motivating purpose" test), found that Dr. Lehmann's report was protected work product without exception; after considering the same evidence, two other courts applying the same restrictive standard found likewise.

In all, thirteen federal and state courts have ruled that Dr. Lehmann's report is protected work product. Only three judges have ruled that Dr. Lehmann's report is discoverable, including the *Tillman* court and *Phillips* court that the plaintiffs discuss, *supra*.[6] None of the judges that have found Dr. Lehmann's report discoverable, however,

[6] The Court should also note that although Dr. Lehmann's report was entered into

considered the testimony and all of the evidence submitted during the *Alexander* evidentiary hearing. In fact, during the *Phillips* trial, Bard offered to submit the *Alexander* testimony and evidence for the court's consideration, but the judge refused to consider Bard's offer of evidence and briefing. Conversely, every court to have considered the testimony and exhibits submitted during the *Alexander* evidentiary hearing has agreed with Bard that Dr. Lehmann's report is protected work product. Finally, a motion remains pending in one case (*Ocasio*) that has been transferred to this Court.

Given the spread of court decisions over the course of more than two years, and the fact that some courts considered extensive evidentiary hearing testimony and exhibits while other courts have not, Bard submits that this Court should consider an early filing of a motion for protective order, applicable to all of the cases, so as to conduct a full review of all of the testimony, the parties' evidence, and the parties' arguments articulated to date, thereby providing an ultimate resolution to this recurring issue. Bard also submits that a resolution of this issue at the outset of this proceeding (before the commencement of extensive discovery) would prevent disputes among the parties about whether the document can be used in depositions.

(ii) Privilege Logs

(a) <u>The Plaintiffs' Position</u>:

Substantial motion practice and sampling will likely be necessary to resolve issues relating to Defendants' extensive claims of work product and attorney-client privilege. In order to expedite the review and resolution of Plaintiffs' challenges to Bard's privilege assertions, Plaintiffs propose the appointment of a Special Master by the Court for this purpose.

Defendants have served multiple privilege logs claiming over 5,000 documents as protected by attorney-client privilege and/or work product in several cases consolidated before this Court. Two small samplings of these privilege logs have been conducted in

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evidence over Bard's repeated objections during the *Phillips* trial, black-letter law provides that compelled production of a document in one case does not waive work-product protection of the document in another case, <u>even when the document at issue becomes part of the public domain</u>.

individual cases. The first sampling involved 50 jointly selected designations and was conducted by the magistrate judge in the *Phillips v. C. R. Bard, Inc., et al.*, action, Civil Action No. 3:12-cv-00344-RCJ-WGC. Defendants withdrew seven of the designations before they could be submitted to the Court. Of the remaining 43 designations, the Court determined that 18 of designations had been improperly withheld. Thus, 50 percent of the documents were improperly withheld as privileged.[7] An additional small sampling was conducted by Judge Sturgeon in *Giordano v. C.R., Bard, Inc., et al.*, action, Civil Action No. 37-2011-00069363. Judge Sturgeon ruled that approximately one-third of the sampled documents had been improperly withheld. Extrapolating these results across the 5,000 privilege claims, suggests that Bard is withholding several thousand relevant documents pursuant to improper claims of privilege and work product. Yet, Bard has only released a handful of documents from its privilege logs since these sampling efforts took place. The appointment of a Special Master to address the privileged document issues at the outset of this litigation will greatly assist the parties in their discovery efforts, which in turn will expedite the preparation of these cases for trial.

Defendants misleading state that two courts have found Defendants' privilege logs to be "adequate" and that plaintiffs are trying to "re-litigate the issue concerning the adequacy of bard's privilege logs." To be clear, what these courts were referring to was the general format of Defendants' privilege logs, not whether Defendants' documents were actually protected. Plaintiff had argued that Defendants should be compelled to modify the privilege logs to include the categories of information identified in *In re Grand Jury Investigation*, 974 F.2d 1068, 1070-71 (9th Cir. 1992), so that plaintiff had sufficient information to evaluate the claimed privilege.[8] The Court held that "In this case, where

[7] Many of the documents deemed privileged by the magistrate related to the Lehmann Report, which the trial judge later ruled was not protected after he had the opportunity to consider the evidence and defenses presented during trial. Thus, in retrospect far more than 50 percent of the sampled documents were improperly withheld.

[8] Specifically, the plaintiff sought an order that the following information be listed:"(a) the attorney and client involved, (b) the nature of the document, (c) all persons or entities shown on the document to have received or sent the document, (d) all persons or entities known to have been furnished the document or informed of its substance, and (e) the date the document was generated, prepared, or dated."

the volume of documents is unquestionably large,…Bard's privilege logs, which identify much of the information outlined in *In re Grand Jury Investigation* and *Dole v. Milonas*, satisfy the requirements of Federal Rule of Civil Procedure 26(b)(5)." *Phillips v. C.R. Bard, Inc*., 290 F.R.D. 615, 638 (D. Nev. 2013). Thus, this finding of "adequacy" Bard refers to has no relevance to the issue that plaintiffs raise above. Plaintiffs' contention is that regardless of the format of Bard's privilege claims, two sampling efforts have shown that Bard is likely withholding several thousand documents under improper claims of privilege and work product. Plaintiffs believe that further sampling and court orders will be required to bring Defendants into compliance with the law.

Finally, Bard argues that because it has already spent a large amount of time removing improper claims of privilege from its privilege logs, the burden should be shifted to plaintiffs to establish that the remaining documents are not privileged. This request is contrary to governing law and should be rejected. First, Bard ignores that these were self-imposed costs, as these documents should have never been withheld in the first place. Second, the law is clear that the burden is on the withholding party establish privilege. *In re Grand Jury Investigation*, 974 F.2d at 1070-71. Thus, the Magistrate Judge in *Phillips* noted that while the format of Bard's privilege logs may be adequate under Rule 26, this did not mean it was sufficient to support a prima facie showing that privilege protects the withheld information. *Phillips*, 290 F.R.D. at 637 (D. Nev. 2013)("This does not mean, however, that for those entries that are challenged by Plaintiff, Bard does not have to make a showing to establish the element of the privilege/work product protection claimed that Plaintiff asserts to be lacking, which may require an affidavit.").

(b) <u>The Defendants' Position</u>:

The plaintiffs' counsel seeks to re-litigate the issue concerning the adequacy of Bard's privilege logs, which was conclusively decided in Bard's favor in 2013, when the court in *Phillips v. C. R. Bard, Inc.* wrote in a 67-page published opinion that "Bard's privilege logs, which identify much of the information outlined in *In re Grand Jury Investigation*, [974 F.2d 1068 (9th Cir. 1992)] and *Dole v. Milonas*, [889 F.2d 885 (9th

Cir. 1989)] satisfy the requirements of Federal Rule of Civil Procedure 26(b)(5)." *Phillips v. C. R. Bard, Inc.*, 290 F.R.D. 615, 638 (D. Nev. 2013). Following that order, the plaintiffs' counsel has repeatedly tried to escape the *Phillips* court's ruling by raising this same issue before numerous other federal and state courts, including in *Giordano v. Bard* (Super. Ct. Cal), where the court also concluded that Bard's privilege logs are adequate.

The fact that multiple courts have concluded that Bard's privilege logs are adequate is not surprising. Bard has expended substantial resources to ensure that its logs meet the requirements of the Federal Rules. Bard completed a comprehensive review of its privilege logs in December 2012 and January 2013, expending over 300 hours of attorney time examining the entries and documents, and revising its logs to ensure that each entry provided sufficient information for the plaintiffs to assess Bard's claim of privilege. Bard also re-evaluated its privilege designations and, where appropriate, withdrew its claim of privilege for approximately 20% of the documents and provided such de-designated documents to the plaintiffs.

Contrary to the plaintiffs' statement, the *Phillips* court addressed much more than the "general format" of Bard's privilege logs. Instead, that court painstakingly evaluated numerous documents for which Bard asserted a claim of privilege, and made specific rulings regarding the merits of Bard's claims. After making these determinations, the *Phillips* court did not order any further sampling of Bard's privilege logs. Following the *Phillips* ruling, Bard undertook a second comprehensive review of its privilege logs, applying the *Phillips* court's order and expending another 225 hours of attorney time reviewing the logs. Bard then produced several revised privilege logs along with approximately 660 files (totaling approximately 2,800 pages) for which it is no longer asserting a claim of privilege.

Taking into consideration the substantial time and expense involved in re-reviewing Bard's privilege logs on two separate occasions and in briefing the privilege log issues before both the *Phillips* court and the *Giordano* court -- as well as the time and expense for the *Phillips* court and the *Giordano* court to issue lengthy rulings on the

sufficiency of Bard's privilege logs and designations -- Bard respectfully submits that additional resources to re-litigate this dispute should not be expended by either the parties or this Court. Respectfully, Bard submits that if the plaintiffs desire to further dispute documents on Bard's privilege logs, they should be required to (1) identify a limited number of specific entries that are disputed (as opposed to categorical assertions with no particularity), and (2) articulate specific arguments why such documents are not privileged. The parties can then meet and confer in good faith regarding the merits of Bard's privilege designations.

(iii) Preservation of Electronically Stored Evidence

(a) <u>The Plaintiffs' Position</u>:

Plaintiffs have reason to believe that Defendants may not have taken adequate steps to ensure adequate preservation of relevant evidence. For example, a Plaintiff in an individual case recently requested that the custodial files of the chain of marketing employees relevant to her case be collected and searched. Specifically, this request sought the custodial files of her local sales representative (Bill Cleary), the District Manager (Tim Jordan), and one of the two regional managers in the country (Bob Cortelezzi). Defendants responded that these custodial files were not preserved, as the employees left the company six or more years ago. Defendants, however, have a policy that requires all departing employees to relinquish and/or destroy all media devices and electronically stored information prior to leaving the company. In the same email, Defendants also confirm that they did not preserve audio recordings from 2006. Yet, Defendants have repeatedly claimed that they were on notice of litigation since 2004, which initiated the obligation to preserve evidence. Further, multiple custodial files that have been produced appear to have substantially less ESI than would be reasonably expected. Given these concerns, Plaintiffs will seek discovery regarding Defendants' preservation efforts, including what preservation communications were made, to whom, and when, what efforts Defendants made to ensure compliance with preservation communications, and what Defendants have done to collect ESI.

(b) The Defendants' Position:

Bard strenuously disagrees with the plaintiffs' claim that Bard has somehow failed to take reasonable steps to preserve discoverable data or that there is any justification that would entitle the plaintiffs to take the extraordinary measure of conducting "discovery about discovery." As a threshold matter, courts routinely prohibit parties from conducting "discovery about discovery" because it does not seek information which is "either relevant or likely to lead to admissible evidence." Moreover, there is no basis to conduct such discovery here, given Bard's good faith preservation efforts over the years. Before litigation even commenced, Bard began issuing legal hold notices in December 2004. Since that time, Bard has periodically updated its legal hold notices and collected and preserved data and documents. In fact, Bard has already collected and produced data from approximately 90 custodians and has produced over 2.5 million pages of documents.

As a basis for their attempt to launch such discovery, the plaintiffs suggest that the absence of data from a small number of employees in an earlier time frame, when Bard had only a couple of filter-related cases pending, is somehow indicative of a general failure to appropriately preserve data. The plaintiffs make that argument, without even evaluating whether those employees had any knowledge relevant to the cases filed at that time. The fact remains that Bard diligently worked, from an early point in time, to preserve data from all of the marketing, engineering, regulatory, quality assurance, and executive personnel involved with the development and marketing of the filter products.

(iv) "Science" Day

In other MDL proceedings, some courts have found it helpful to schedule a time during a case management conference for the parties to make brief presentations about the product(s) involved in the litigation, the medical and scientific literature regarding the product(s), and the technical issues involving the product(s). Counsel for both the plaintiffs and the defendants in this litigation have participated in such presentations in other MDLs, and found them useful for the Court and for the parties. If this Court believes similar presentations would be beneficial in this MDL, the parties stand ready to

schedule a time that would be convenient for the Court.

l. Should the Court set a firm date by which cases will be remanded to transferor courts?

(i) The Plaintiffs' Position:

For the reasons stated herein, Plaintiffs do not believe that a firm date for remand of all cases back to their transferor courts is appropriate at this time. This is an issue that can be revisited later in the litigation as discovery progresses.

(ii) The Defendants' Position:

For the reasons set forth previously submitted in this submission, Bard believes that no specific deadline for the remand of cases should be set at this time. Instead, Bard respectfully suggests that the Court and the parties work toward conducting a bellwether trial in the context of this MDL.

DATED this 9th day of October, 2015.

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of October, 2015, I electronically filed **THE PARTIES' PROPOSED AGENDA AND DISCUSSION OF ISSUES SUBMITTED PURSUANT TO THE COURT'S SEPTEMBER 15, 2015 ORDER SETTING INITIAL CASE MANAGEMENT CONFERENCE** with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

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